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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,255	07/10/2006	Toshio Miyata	2006_0834A	1843

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EXAMINER	
SZNAIDMAN, MARCOS L	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
02/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,255	MIYATA ET AL.	
	Examiner	Art Unit	
	MARCOS SZNAIDMAN	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *22 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *9* is/are allowed.

6)☒ Claim(s) *24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicant's reply filed on October 22, 2008.

Status of Claims

Claims 9 and 24 are currently pending and are the subject of this office action.

Claims 9 and 24 are currently under examination.

Priority

The present application is a 371 of PCT/JP04/18038 filed on 12/03/2004, and claims priority to foreign application: JAPAN 2003-407834 filed on 12/05/2003.

Rejections and/or Objections and Response to Arguments

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 (New Rejection not Necessitated by Amendment)

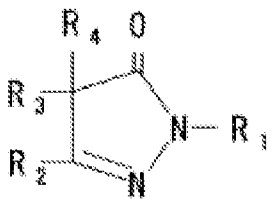
The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 24 recites a compound of general formula: I:



Wherein R4 is a hydrogen or monovalent organic group, R1 is phenyl, R2 is methyl, and R3 is 6-methyl-1,3-dihydrofluoro-[3,4-c]-pyridin-7-ol group.

M.P.E.P. #2163 states: "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention….one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process".

A description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial

portion of the members of the genus, which features constitute substantial portion of the genus. See *Univ. of California vs. Eli Lilly*, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under section 112 first, by showing enablement of a representative number of species within the genus. A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus.

Applicant has failed to show that he was in possession of all the diverse compounds encompassed by the above general formula, which encompasses millions of compounds. Applicant discloses the structure of formula I only for R4 hydrogen (see compounds 68 and 69 on pages 41-42 of the specification). There are no other examples of compounds wherein R4 is a monovalent organic group. The disclosed compound can not be viewed as being reasonable representative of the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided, other than the disclosure of those two specific examples.

Although applicant defines the term “monovalent organic group” on page 34 of the specification, the term still includes a large number and variety of substituents like 3 to 7 membered heterocyclic groups, substituted hydrocarbons, etc

Given the broad scope of the claimed subject matter, Applicant has not provided sufficient written description that would allow the skilled in the art to recognize all the compounds of the above general formula I claimed.

Claim Rejections - 35 USC § 112 (New Rejection not Necessitated by Amendment)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds 68 and 69 of the specification (Wherein R4 is a hydrogen, R1 is phenyl, R2 is methyl, and R3 is 6-methyl-1,3-dihydrofluoro-[3,4-c]-pyridin-7-ol group), does not reasonably provide enablement for all the compounds claimed in general formula I, wherein R4 is a monovalent organic group.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This is a scope of enablement rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996). As pointed out by the court in *In re Angstadt*, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman*, 230 USPQ 546 (Bd. Apls. 1986) at 547 the court recited eight factors:

1- the quantity of experimentation necessary,

2- the amount of direction or guidance provided,

3- the presence or absence of working examples,

4- the nature of the invention,

5- the state of the prior art,

6- the relative skill of those in the art,

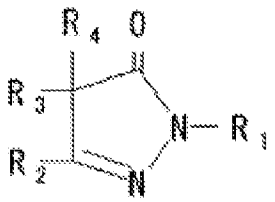
7- the predictability of the art, and

8- the breadth of the claims

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the *Wands* factors are relevant to the instant fact situation for the following reasons:

1. <u>The nature of the invention</u>

Claim 24 recites a compound of general formula: I:



Wherein R4 is a hydrogen or monovalent organic group, R1 is phenyl, R2 is methyl, and R3 is 6-methyl-1,3-dihydrofluoro-[3,4-c]-pyridin-7-ol group.

2. The relative skill of those in the art

The relative skill of those in the art is high, generally that of an M.D. or Ph.D. The artisan using Applicant's invention would generally be a physician with a M.D. degree and several years of experience.

3. The state and predictability of the art

Since the compounds of claim 24 are novel there is no synthetic procedure for these particular compounds in the prior art.

It is well know in the prior art that organic synthesis is still an experimental science. Even though the knowledge of organic synthesis and the arsenal of chemical reactions have exploded in the last decades, there is still a high degree of unpredictability in organic synthesis. See for example Dorwald F. A. (Side reactions in organic synthesis, 2005, Wiley, VCH, Weinheim, pg. IX of Preface) where it says: " Most non-chemists would probably be horrified if they were to learn how many attempted synthesis fail, and how inefficient research chemists are. The ratio of successful to

unsuccessful chemical experiments in a normal research laboratory is far below unity, and synthetic research chemists, in the same way as most scientists, spend most of their time working on what went wrong, and why. He later states: “The final synthesis usually looks like quite different from that originally planned, because of unexpected difficulties encountered in the initially chosen synthetic sequence. Only the seasoned practitioner who has experienced for himself the many failures and frustrations which the development (sometimes even repetition) of a synthesis usually implies will be able to appraise such work”. And finally: “Chemists tend not to publish negative results, because these are, as opposed to positive results, never definitive (and far too copious)."

4. The breadth of the claims

Claim 24 is very broad in terms of the number of compounds claimed.

5. The amount of direction or guidance provided and the presence or absence of working examples

Applicant provides a synthetic procedure for compounds 68 and 69 (see specification page 22, wherein R4 is Hydrogen and a general synthetic procedure on pages 43-44, however no examples are provided wherein R4 is a monovalent organic group.

6. The quantity of experimentation necessary

As discussed above (see: 3. the state and predictability of the art), small changes in the structure of one of the reagents could cause a completely different synthetic outcome (i.e. different products, lower yields or no reaction at all). Based on this, and since applicant claims such a diverse set of substituents on R4 (monovalent organic groups) (see: 5. The amount of direction or guidance and the presence or absence of working examples above) it is expected that some, if not most of the R4 substituents recited in claim 24 (except for hydrogen) will not provide the desired synthetic outcome outlined by applicant on pages 43-44 of the specification.

So, determining how to make a particular compound with an R4 group different than hydrogen would require testing of new synthetic pathways for the different compounds. This is undue experimentation given the limited guidance and direction provided by Applicants.

7. Conclusion

Accordingly, the invention of claim 24 does not comply with the scope of enablement requirement of 35 U.S.C 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation with no assurance of success.

Allowable Subject Matter

Claim 9 is allowed.

Withdrawn Rejections and/or Objections

Claims rejected under 35 USC 112, second paragraph

Due to applicant's amendment of claim 9, the 112, second paragraph rejection is now moot.

Rejection under 35 USC 112, second paragraph is withdrawn.

Conclusion

Claim 9 is allowed.

Claim 24 is rejected.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is

(571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1612
February 4, 2009

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642